



7020-02

INTERNATIONAL TRADE COMMISSION

Investigation No. 337-TA-1189

Certain Dissolving Microneedle Patches for Cosmetic and Pharmaceutical Use

Institution of Investigation

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 21, 2019, under section 337 of the Tariff Act of 1930, as amended, on behalf of TheraJect, Inc. of Fremont, California. Supplements were filed on November 27 and December 2, 2019. A first amended complaint was filed on December 10, 2019, and a second amended complaint was filed on December 19, 2019. The second amended complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dissolving microneedle patches for cosmetic and pharmaceutical use by reason of infringement of certain claims of U.S. Patent No. 6,945,952 (“the ’952 patent”). The second amended complaint further alleges that an industry in the United States is in the process of being established as required by the applicable Federal Statute.

The second amended complaint requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

Addresses: The second amended complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Room 112, Washington, D.C. 20436, telephone (202) 205-2000. Hearing impaired individuals are advised

that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2019).

Scope of Investigation: Having considered the second amended complaint, the U.S.

International Trade Commission, on January 9, 2020, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1-13 of the '952 patent; and whether an industry in the United States is in the process of being established as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "dissolving microneedle patch[es]";

(3) Pursuant to section 210.10(b)(3) of the Commission's Rules of Practice and Procedure, 19 CFR § 210.10(b)(3), the presiding Administrative Law Judge shall hold an early evidentiary hearing, find facts, and issue an early decision, within 100 days of institution except for good cause shown, as to whether the complainant has satisfied the economic prong of the domestic industry requirement. Notwithstanding any Commission Rules to the contrary, which are hereby waived, any such decision should be issued in the form of an initial determination (ID) under Commission Rule 210.42(a)(3), 19 CFR 210.42(a)(3). The ID will become the Commission's final determination 30 days after the date of service of the ID unless the Commission determines to review the ID. Any such review will be conducted in accordance with Commission Rules 210.43, 210.44, and 210.45, 19 CFR 210.43, 210.44, and 210.45. The issuance of an early ID finding that the complainant does not satisfy the economic prong of the domestic industry requirement shall stay the investigation unless the Commission orders otherwise; any other decision shall not stay the investigation or delay the issuance of a final ID covering the other issues of the investigation;

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

TheraJect, Inc.

39270 Paseo Padre #112

Fremont, CA 94538

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the second amended complaint is to be served:

Raphas Co., Ltd

(07793) 62, Magokjingang 8-ro-1-gil,

Gangseo-gu, Seoul

Republic of Korea

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the second amended complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the second amended complaint and the notice of investigation. Extensions of time for submitting responses to the second amended complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the second amended complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the second amended complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the second amended complaint and this notice and to enter an initial

determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa Barton
Secretary to the Commission

Issued: January 10, 2020

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